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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/694,032 | 10/27/2003 | James D. Hughett | 0341-0003.14 | 3894 |

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| EXAMINER | |
|---|---|
| SCHELL, LAURA C | |
| **ART UNIT** | **PAPER NUMBER** |
| 3767 | |

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
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| 3 MONTHS | 01/26/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/694,032 | HUGHETT ET AL. | |
| | Examiner | Art Unit | |
| | Laura C. Schell | 3767 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *05 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *10,11 and 20-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10,11 and 20-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/27/03-8/7/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

Applicant's response indicating that the previous restriction requirement was improper is acknowledged. Claims 10, 11 and 20-23 are pending in this application and addressed in this office action.

### *Information Disclosure Statement*

The following foreign patent documents listed on the IDS submitted on 10/27/03 have not been considered as copies of these documents have not been submitted : DE 1095963; GB 1219604; SU 279814; GB 1558127; CAI197631). The international search report also listed on the above-named IDS has also not been considered as it was not submitted.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liprie (US Patent No. 6,635,008) in view of Waksman et al. (US Patent No. 7,160,238). Liprie discloses the device substantially as claimed including: a transfer device usable in a system for intraluminal treatment of a selected site in a body of a patient (Fig. 2) by at least one treating element (Fig. 1a, 19) advanced through a lumen in the transfer device (Fig. 3, 56) into a lumen of a separate catheter (24), the transfer device being adapted to receive a source cartridge (30) for storing the treating element, a system for preventing operation of the transfer device unless each of the catheter and source cartridge are attached thereto comprising: an illumination source and optical sensor located in the transfer device in proximity to where each of the catheter source cartridge is received by the transfer device, each illumination source being located with respect to its optical sensor so that the optical sensor is able to receive light from its illumination source only if the catheter, fluid cartridge or source cartridge is not received by the transfer device, and the optical sensor being blocked from receiving light from the illumination source when the catheter, fluid cartridge or source cartridge are received by the transfer device (col. 7, line 64 through col. 8, line 5); a microprocessor for controlling the movement of the treating element from the transfer device to the catheter (col. 2, lines 13-17), the microprocessor preventing operation of the transfer device upon receiving a signal from any of the optical sensors indicating that at least one of the catheter, fluid cartridge and source cartridge is not attached to the transfer device (col. 8, lines 6-22).

Liprie, however, does not specifically disclose that the treating element is advanced through the transfer device by means of pressurized fluid. Waksman, however, discloses that it is common within the art to advance radioactive treating elements through the lumen of a catheter by means of a pressurized fluid (abstract). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have known to use Liprie's device with a pressurized fluid source/cartridge as taught by Wakman (Fig.1, 14; Fig. 2, 40) in order to move the treating element from the transfer device into a catheter lumen and to the treatment site.

In reference to claim 11, Liprie discloses a graphical interface controlled by the microprocessor for visually indicating which one of one ore more of the catheter, fluid cartridge and source cartridge is not attached to the catheter when operation of the transfer device is prevented (col. 8, lines 19-22).

Claims 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Waksman et al. (US Patent No. 7,160,238) in view of Spako et al. (US Patent no. 5,103,395). Waksman discloses the device substantially as claimed including: a transfer device (Fig. 2a) usable in a system for intraluminal treatment of a selected site in a body of a patient by at least one treating element advanced from a translucent storage sleeve (52) having a lumen into a lumen of a separate catheter (Fig. 1, "catheter") by means of pressurized fluid (abstract). Waksman, however, does not disclose a system for detecting the presence or absence of the treating element. Spako, however discloses a system for detecting the presence or absence of the

treating element in the translucent storage sleeve comprising (; a light source including a jacketed fiber optic bundle disposed on a first side of the storage sleeve to produce a plane of light that intersects at least a portion of the storage sleeve lumen; a linear array of photo sensors disposed on a second side of the storage sleeve so as to measure light from the light source; a microprocessor for' comparing the amount of light measured by the photo sensors to a reference amount corresponding to the amount of light measured by the photo sensors when the treating element is not within the lumen of the storage sleeve (col. 12, lines 67 through col. 13, line 65). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Waksman's device with the sensors, as taught by Spako, in order to determine whether or not the treating element was in place before treatment.

In reference to claims 21 and 22, Waksman discloses the device substantially as claimed, except for the light sources comprising an infrared or laser diode source. Spako, however, discloses that the light source can be a light emitting diode source (col. 13, lines 7-8). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Waksman with the led as taught by Spako, in order to provide a compact light emitting source for a handheld device, such as Waksman's.

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Liprie (US Patent No. 6,635,008) in view of Waksman et al. (US Patent No. 7,160,238). Liprie discloses the device substantially as claimed including: a transfer device usable in a

system for intraluminal treatment of a selected site in a body of a patient (Fig. 2) by at least one treating element (Fig. 1a, 19) advanced through a lumen in the transfer device (Fig. 3, 56) into a lumen of a separate catheter (24), the transfer device being adapted to receive a source cartridge (Fig. 3, 30) for storing the treating element, a system for preventing operation of the transfer device unless each of the catheter, fluid cartridge and source cartridge are attached thereto comprising: a sensor located in the transfer device in proximity to where each of the catheter, fluid cartridge and source cartridge is received by the transfer device, each sensor generating a signal based on whether each of the catheter, fluid cartridge or source cartridge is received by the transfer device (col. 7, line 64 through col. 8, line 5); a microprocessor for controlling the movement of the treating element from the transfer device to the catheter, the microprocessor preventing operation of the transfer device upon receiving a signal from any of the sensors indicating that at least one of the catheter, fluid cartridge and source cartridge is not attached to the transfer device (col. 8, lines 6-22).

Liprie, however, does not specifically disclose that the treating element is advanced through the transfer device by means of pressurized fluid. Waksman, however, discloses that it is common within the art to advance radioactive treating elements through the lumen of a catheter by means of a pressurized fluid (abstract). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have known to use Liprie's device with a pressurized fluid source/cartridge as taught by Wakman (Fig.1, 14; Fig. 2, 40) in order to move the treating element from the transfer device into a catheter lumen and to the treatment site.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura C. Schell whose telephone number is (571) 272-7881. The examiner can normally be reached on Monday-Friday 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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